

Drug Enforcement Administration, Justice

§ 1309.21

MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

- 1309.61 Modification in registration.
- 1309.62 Termination of registration.
- 1309.63 Transfer of registration.

SECURITY REQUIREMENTS

- 1309.71 General security requirements.
- 1309.72 Felony conviction; employer responsibilities.
- 1309.73 Employee responsibility to report diversion.

AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

SOURCE: 60 FR 32454, June 22, 1995, unless otherwise noted.

GENERAL INFORMATION

§ 1309.01 Scope of part 1309.

Procedures governing the registration of manufacturers, distributors, importers and exporters of List I chemicals pursuant to Sections 102, 302, 303, 1007 and 1008 of the Act (21 U.S.C. 802, 822, 823, 957 and 958) are set forth generally by those sections and specifically by the sections of this part.

§ 1309.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1309.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Drug Enforcement Administration, Chemical Operations Section, Office of Diversion Control, Washington, D.C. 20537.

FEES FOR REGISTRATION AND REREGISTRATION

§ 1309.11 Fee amounts.

(a) For each initial registration to manufacture for distribution, distribute, import, or export, the applicant shall pay a fee of \$595 for a annual registration.

(b) For each reregistration to manufacture for distribution, distribute, im-

port, or export, the registrant shall pay a fee of \$477 for an annual registration.

(c) For each initial registration to conduct business as a retail distributor the applicant shall pay an application processing fee of \$7 and an investigation fee of \$248, for an annual registration.

(d) For each reregistration to conduct business as a retail distributor the registrant shall pay a fee of \$116.

§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture for distribution, distribute, import, or export, the applicant shall pay the fee when the application for registration or reregistration is submitted for filing.

(b) For retail the distributor initial applications, the applicant shall pay the application processing fee when the application for registration is submitted for filing. The investigation fee shall be paid within 30 days after DEA notifies the applicant that the preregistration investigation has been scheduled.

(c) For retail distributor reregistration applications, the registrant shall pay the fee when the application for reregistration is submitted for filing.

(d) Payments should be made in the form of a personal, certified, or cashier's check or money order made payable to "Drug Enforcement Administration." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

[60 FR 32454, June 22, 1995; 60 FR 35264, July 6, 1995]

REQUIREMENTS FOR REGISTRATION

§ 1309.21 Persons required to register.

(a) Every person who distributes, imports, or exports any List I chemical, other than those List I chemicals contained in a product exempted under §1300.02(b)(28)(i)(D) of this chapter (irrespective of the threshold provisions under §1300.02(b)(28)(i)(D)(2) of this chapter), or who proposes to engage in

§ 1309.22

the distribution, importation, or exportation of any List I chemical, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§1309.24 through 1309.26 of this part. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(b) Every person who distributes or exports a List I chemical they have manufactured, other than a List I chemical contained in a product exempted under §1300.02(b)(28)(i)(D) of this chapter, or proposes to distribute or export a List I chemical they have manufactured, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§1309.24 through 1309.26 of this part.

[67 FR 14860, Mar. 28, 2002]

§ 1309.22 Separate registration for independent activities.

(a) The following groups of activities are deemed to be independent of each other:

- (1) Retail distributing of List I chemicals;
- (2) Non-Retail distributing of List I chemicals;
- (3) Importing List I chemicals; and
- (4) Exporting List I chemicals.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§1309.24 through 1309.26, except that a person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.

[60 FR 32454, June 22, 1995, as amended at 61 FR 32926, June 26, 1996; 67 FR 14860, Mar. 28, 2002]

§ 1309.23 Separate registration for separate locations.

(a) A separate registration is required for each principal place of busi-

21 CFR Ch. II (4–1–05 Edition)

ness at one general physical location where List I chemicals are distributed, imported, or exported by a person.

(b) The following locations shall be deemed to be places not subject to the registration requirement:

(1) A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered; and

(2) An office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders.

§ 1309.24 Waiver of registration requirement for certain activities.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment.

(b) The requirement of registration is waived for any person who distributes a product containing a List I chemical that is regulated pursuant to §1300.02(b)(28)(i)(D), if that person is registered with the Administration to manufacture, distribute or dispense a controlled substance.

(c) The requirement of registration is waived for any person who imports or exports a product containing a List I chemical that is regulated pursuant to §1300.02(b)(28)(i)(D), if that person is registered with the Administration to engage in the same activity with a controlled substance.

(d) The requirement of registration is waived for any person who distributes a prescription drug product containing a List I chemical that is regulated pursuant to §1300.02(b)(28)(i)(D) of this chapter.

(e) The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are limited to the distribution of below-threshold quantities of a